NOV - 1 2004

510(k) SUMMARY

SUBMITTER:	Gambro Renal Products 10810 West Collins Avenue Lakewood, CO 80215
CONTACT:	Thomas B. Dowell, Manager Regulatory Affairs Phone: (303) 231-4094 Fax: (303) 542-5138
DATE PREPARED:	February 6, 2004
DEVICE NAME:	GamCath® High Flow Catheter 13 French 12.5 cm 13 French 15 cm 13 French 17.5 cm 13 French 20 cm 13 French 25 cm
COMMON/UNUSUAL NAME:	Short-Term Hemodialysis Catheter
CLASSIFICATION NAMES:	MPB – Catheter, Hemodialysis, Non Implanted [21 CFR 876.5540(b)(2)] – Non Implanted Blood Access Device
CLASSIFICATION:	Class II per 21 CFR 876.5540(b)(2)
PREDICATE DEVICE:	Niagara™ Slim-Cath™ Straight: 12 French, 15, 20 and 24 cm Precurved: 12 French, 12.5, 15 and 20 cm K010778; April 13, 2001

DEVICE DESCRIPTION:

The catheter is a device, which can be used for short-term (less than 30 days) vascular access for hemodialysis, hemoperfusion and apheresis via the jugular, subclavian or femoral veins.

The catheter is available in 13 French (4,3 mm / 0,169") straight configuration with the following insertion length: 125mm (4,921"), 150mm (5,906"), 175mm (6,900"), 200mm (7,874") and 250mm (9,843").

The catheter body and hub (bifurcation) is made from aliphatic polyurethane. The catheter body and hub is radiopaque (filled with Barium Sulfate).

The catheter body has two lumens positioned side by side. The cross section of the venous lumen is elliptical and the cross section of the arterial lumen is kidney-shaped. The arterial lumen is beveled. The venous lumen extends beyond the arterial lumen with a rounded tip.

The arterial and venous extension line is made from transparent aliphatic polyurethane, which is connected to the hub. On each extension line there is a clamp with safety insert. The clamps are color coded to indicate the arterial lumen (red) and venous lumen (blue).

The insertion length, diameter and priming volume are printed on the safety inserts.

The Luer-Lock connectors are made from rigid PVC connected to the extension line. The Luer-Lock connector is protected with a Luer-Lock protection cap.

A stylet made of FEP is provided in the venous lumen for insertion.
A rotary suture ring is assembled with the hub (bifurcation) for fixation of the device.

The brand name of the device is printed on the hub (bifurcation).

INTENDED USE:

GamCath® catheters are indicated for use in attaining short-term vascular access for hemodialysis, hemoperfusion and apheresis therapy via the jugular, subclavian or femoral vein. Not for pediatric use.

Technological Characteristics:

The proposed device configurations have the same technological characteristics and are similar in design, function, composition, and operation, to the currently marketed devices on the market.

Performance Data:

The performance data demonstrate that the GamCath® High Flow Catheter is substantially equivalent to the predicate devices currently available on the market.

The tests were performed per Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 03/16/95.

Conclusions:

Testing performed on the GamCath® High Flow Catheter indicates that they are safe, effective and perform as well as the predicate devices, when used in accordance with the instruction for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 1 2004

Mr. Thomas B. Dowell
Manager Regulatory Affairs
Gambro® Renal Products
10810 W. Collins Avenue
LAKEWOOD CO 80215

Re: K040301
Trade/Device Name: GamCath® High Flow Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: 78 MPB
Dated: September 24, 2004
Received: September 27, 2004

Dear Mr. Dowell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION XII

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K040301

Device Name: GamCath® High Flow Catheter

Indications For Use:

GamCath® catheters are indicated for use in attaining short-term vascular access for hemodialysis, hemoperfusion and apheresis therapy via the jugular, subclavian or femoral vein. Not for pediatric use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040301